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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,799	11/21/2005	Dieter Herrmann	2970-125	7706
6449	7590	12/19/2007	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			CRANE, LAWRENCE E	
			ART UNIT	PAPER NUMBER
			1623	
			NOTIFICATION DATE	DELIVERY MODE
			12/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/549,799	HERRMANN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	L. E. Crane	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on Aug. 21, Sept. 17, & Nov. 19, 2007(amdt).
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-8 and 13-20 is/are allowed.
- 6) Claim(s) 9-11 is/are rejected.
- 7) Claim(s) 12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

No claims have been cancelled, claims **1-3, 8, 12, 13-14 and 17** have been amended, the disclosure has not been amended, and no new claims have been added as per the amendments filed August 21, 2007, September 17, 2007 and November 19, 2007. No additional or supplemental Information Disclosure Statements (IDSs) filed September 19, 2005 and November 21, 2005 have been received as of the date of this Office action. A declaration filed under 37 C.F.R. §1.132 on September 17, 2007 and signed by co-applicant Mlle. Heckl-Östreicher has also been received with supplemental experimental data filed separately on November 19, 2007.

Applicant query: Claim 13 includes an amendment as noted above, but is listed by applicant in the status "(Withdrawn)." Applicant is respectfully requested to further define or clarify the status of claim 13.

Claims 1-20 remain in the case, but claim 13 may have been withdrawn.

Note to applicant: when a rejection refers to a claim X at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims 9-11 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the inhibition of the growth of human lung carcinoma by a single active ingredient, does not reasonably provide enablement for the treatment of any other neoplastic disease condition or for the administration a pharmaceutical composition wherein there is more than one active ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8

USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

- A. The breadth of the claims: The instant pharmaceutical composition claim and method of treatment claims are directed to compositions containing multiple active ingredients, and to methods of treating all "malignant tumors" by administration of a single active ingredient, or by administration of multiple active ingredients wherein the additional active ingredients are only defined generically in claim 11.
- B. The nature of the invention: The invention is directed to conjugates of certain purine nucleotides and glycerides, pharmaceutical compositions thereof, the administration of said conjugates to treat tumors, and a method of making said conjugates.
- C. The state of the prior art: The prior art of record does not disclose references other than applicant's priority documents and related publications wherein the instant subject matter has been disclosed.
- D. The level of one of ordinary skill: One of ordinary skill would be knowledgeable concerning how to make nucleotide conjugates of the kind claimed and how to determine an effective dosage for medicinally appropriate administration thereof in the treatment of tumors.
- E. The level of predictability in the art: In view of the small amount of biological data provided the level of predictability is very low.
- F. The amount of direction provided by the applicant: Only a single example of a single active ingredient claimed herein has been provided wherein a single neoplastic disease condition has been effectively treated.
- G. The existence of working examples: This subject is described in the previous paragraph.
- H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive in view of the minimum amount of biological test data provided.

Applicant's arguments and responses filed August 21, 2007, September 17, 2007 and November 19, 2007 have been fully considered but they are not persuasive.

Examiner has reviewed the declaration provided by co-applicant Mlle. Heckl-Ostreicher, and has noted that all of the examples therein, and all of the method of treating data in the disclosure, is directed to the treatment of various carcinomas, but not to any other variety of the neoplastic diseases included under generic terms including "cancer" and "malignant tumor." Therefore, examiner respectfully suggests that the allowable subject matter within the scope of claim 12 is limited to "carcinomas" and that a dependent claim with a (Markush?) listing of the specifically exemplified carcinomas in a dependent claim would provide applicant all of the subject matter presently found to be reasonably enabled. Examiner further suggests that the subject matter of claim 11 is inherently included by any method claim meeting the above defined limits and wherein the term of art "comprising" is present because the noted term of art would provide coverage for all claims wherein the instant defined active ingredients are included as part of a more complex mixture of active ingredients, and therefore that claim 11 should be cancelled without prejudice.

Claim 12 is objected to because of the following informalities:

In claim 12 at lines 6, 10, and 11, there are several typographical errors: a subscript number not shown as a subscript at lines 6 and 10; and 5 extra spaces are present at lines 10 and 11.

Appropriate correction is required.

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new grounds of objection.

Claim 11 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11 the term "other anticancer agents" is incomplete because this generic term has not been further defined by a listing of the other particular agents intended to be included within the metes and bounds of the claim.

Applicant's arguments and responses filed August 21, 2007, September 17, 2007 and November 19, 2007 have been fully considered but they are not persuasive.

Applicant is referred to the comments following the immediately preceding rejection.

Claim 12 is objected to as containing various minor errors the correction of which would render the claim allowable.

Claims 1-8 and 13-20 appear to be allowable as presently in the case.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <<http://pair-direct.uspto.gov>>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec  
12/11/2007



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